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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,815	10/26/2001	Renu Wadhwa	06501-091001 / C1-104PCT-	2880

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225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,815	WADHWA ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 11-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/09/2002*, 04/02/2002, 08/05/2002
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Exhibits A, and B, C*

DETAILED ACTION

Election/Restrictions

Claims 1-8, 11-23 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/01/2004.

Applicant's election without traverse of group VI, encompassing claims 9, and 10 in the reply filed on 07/01/2004 is acknowledged. It is noted that applicant may seek rejoinder of claims 16, and 17 when the elected claims 9, and 10 are found allowable. Claims 1-23 are pending. Claims 9, and 10 are examined on merits to the extent they are drawn to SEQ ID NO:4.

Claim Objections

Claims 9, and 10 are objected to because of the following informalities: Claims 9, and 10 depend on the non-elected claims 1, and 2. Appropriate correction is required. For the purpose of this Office action, all of the limitations of claims 1, and 2 will be included in the examination of claims 9, and 10. However, this treatment does not relieve applicant the burden of responding to this objection.

Claims 9, and 10 are also objected because applicant has not amended the claims to reflect the election. The claims are still drawn to multiple inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 depends on claim 1, which recites "under stringent conditions" in step (d), line 1, but it is not clear what the metes and bounds are. The term "under stringent conditions" is a relative term, which renders the claim indefinite. The term " under stringent conditions " is not defined by the claim. The specification at paragraph 46 discloses exemplary conditions, but the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This

written description rejection is made because the claims are interpreted as drawn to genus of polypeptides.

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claim 9 that depends on claim 1 (b) is interpreted as drawn to genus of polypeptide encoded by a nucleic acid comprising less than the full open reading frame (ORF) i.e. "a coding region" (the broadest possible interpretation of "a coding region" is any segment of the full-length ORF); the claim does not specify what function is correlated with the genus of proteins that minimally contain "a coding region" of a full-length ORF gene product.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page

1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptide, given that the specification has only described SEQ ID NO: 4. Therefore, only substantially purified polypeptide comprising SEQ ID NO:4, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim 9 as concurrently construed encompass full-length proteins encoded by differently spliced isoforms, allelic variants, or other species homologs that minimally contain "a coding region of SEQ ID NO:3. The specification at paragraph at bridging pages 5, and 6 discloses that the nature of the claimed invention encompasses "proteins functionally equivalent to the Gros1 proteins. Such proteins include, for example, homologous proteins of other organisms corresponding to the human or mouse Gros1 protein, as well as mutants of human or mouse Gros1 proteins."

There is substantial variability among the species of polypeptides encompassed within the scope of the claims, because instant claims are drawn to any polypeptide minimally contains a fragment of SEQ ID NO:4. They are structurally unrelated. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by amino acids sequences, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Since the breath of the claims as

reading on a polypeptides encoded by different spliced isoforms, allelic variants, and/or variants from different species yet to be discovered, the lack of correlation between the structure and the function of the genes, it is concluded that the written description requirement is not satisfied.

Claims 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:4 for "cell proliferation inhibitory activity" i.e. anti-growth activity, does not reasonably provide enablement for fragments and mutants for anti-growth antivity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

This scope of enablement rejection is made because the Office interprets that the nature of the claimed invention is "a functionally equivalent" to SEQ ID NO:4 or fragment of SEQ ID NO:4.

The specification at page 6, lines 3-7 defines the term "functionally equivalent" as "the subject protein has the activity to inhibit cell proliferation like Gros1 proteins. Whether the subject protein has a cell proliferation inhibitory activity or not can be judged by introducing the DNA encoding the subject protein into a cell, such as NIH-3T3, expressing the protein, and detecting repression of proliferation of the cells or reduction in colony forming activity." However, the specification does not teach which residues could be important for the activity.

It is well known in the art that even slight modifications in a peptide or protein structure and can have significant and unpredictable effects on biological activity. Bowie et al (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out biological activity and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (col 1, p. 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (col 2, p. 1306). The sensitivity of proteins to alterations of even a single amino acid (including

conservative substitutions) in a sequence are exemplified by Burgess et al (J of Cell Bio. 111:2129-2138, 1990) who teach that replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein and by Lazar et al (Molecular and Cellular Biology, 1988, 8:1247-1252) who teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or even with conservative glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein. The specification does not teach the specific structures responsible for anti-growth activity in colony forming assay, nor provide guidance as to what changes in the structure can be made retaining anti-growth activity.

Considering the unpredictable state of art, limited guidance, no examples in the specification how to use various fragments and mutants, broad breath of the claims, it is concluded that undue experimentation is required to practice the full scope of the claimed invention.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

However, applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

See 102 (a) rejection below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by Wassenhove-McCarthy et al., (IDS, August 27, 1999, J. Biol. Chem. vol. 274, pages 25004-25017).

Claim 9 depends on the non-elected claim 1. Based on the limitation of claim 1 (b), i.e. the open transitional phrase "comprising" along with "a coding region" of SEQ ID NO:3, which is interpreted as "an unspecified length" of SEQ ID NO:3 (see written description rejection above for further detail), claim 9 is interpreted as drawn to a purified polypeptide comprising a polypeptide encoded by an unspecified length of "a coding region" of SEQ ID NO:3.

Wassenhove-McCarthy et al., teach a 747 amino acids polypeptide that is 87.3 % identical to instant SEQ ID NO:4. Note Exhibit A (sequence alignment). This rejection could be obviated by submitting the certified translation of the

foreign priority document i.e. JP 11/118806 filed on 04/26/1999, or by amending the claim to exclude the species taught by the prior art.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Daigo et al., (April 15, 1999, Cancer Research, vol. 159, pages 1966-1972).

The broadest reasonable interpretation of the scope of the claimed invention includes any isolated protein that has even one amino acid in common with instant SEQ ID NO:4 in order to meet the structural limitation of claim 9, since claim (c) says any number “one or more” of amino acids could be mutated, deleted, or added. As stated above, "functionally equivalent" is defined as “the subject protein has the activity to inhibit cell proliferation like Gros1 proteins. Whether the subject protein has a cell proliferation inhibitory activity or not can be judged by introducing the DNA encoding the subject protein into a cell, such as NIH-3T3, expressing the protein, and detecting repression of proliferation of the cells or reduction in colony forming activity.”

Daigo et al., teach a polypeptide that at Fig.2 an isolated 1755 amino acids protein with amino acids PD at #673 and 674 that matches to PD at #390 and 391 of instant SEQ ID NO:4. See Exhibit B (sequence alignment). Daigo et al., teach that introduction of the cDNA significantly suppresses the growth of the four different cancer cell lines. See the abstract, and colony-formation assay data shown in Table 1. Thus, the polypeptide disclosed at Fig. 2 of Daigo et al., meets the structural and functional limitation of instant claim 9.

Claims 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 89/04875 (1 June 1989).

Since claim 9 depends on claim 1 (b) reciting "a coding region" of an unspecified length (see written description rejection above for further detail), claim 9 is interpreted as drawn to a polypeptide that matches at least two contiguous amino acids SEQ ID NO:4. Claim 10 is also interpreted as drawn to a polypeptide that matches at least two contiguous amino acids SEQ ID NO:4. Neither the instant claims nor the instant specification define how many amino acids should be the claimed "polypeptide". Merriam-Webster Online Dictionary (downloaded from url>>www.m-w.com on 8/21/04) defines "polypeptide" as a molecular chain of amino acids. Therefore, the broadest reasonable interpretation of "polypeptide" is a molecule comprising minimally two amino acids.

WO 89/04875 at page 59 line 11 i.e. claim 14 (a) teaches an isolated polypeptide consisting of "GPPAA", which is a fragment of instant SEQ ID NO:4 (i.e. residues 125 to 129 of instant SEQ ID NO:4). WO 89/04875 at page 58 line 3 i.e. claim 9 (a) also teaches an isolated nucleic acid GGGCCGCCTGCCGCC encoding GPPAA". Note Exhibit C (sequence alignment). Thus, WO 89/04875 teaches instant claims 9, and 10.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone

number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

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DR   InterPro; IPR008941; TPR-like.
DR   Pfam; PF03171; 2OG-FeII_Oxy; 1.
DR   SMART; SM00702; P4Hc; 1.
DR   PROSITE; PS00014; ER_TARGET; 1.
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Qy        238 AYEECRALCEGPYDYDGYNYLEYNADLFQAITDHYIQVLNCKQNCVTELASHPSREKPFE 297
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Qy        298 DFLPSHYNYLQFAYYNIGNYTQAGECAKTYLLFFPNDEVMNQNLAYYAAMLGEEHTRSIG 357
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Qy        418 SQEIGNLMKEIETLVEEKTKESLDVSRLTREGGPLLYEGISLTMNSKLLNGYQRVVMDGV 477
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Qy        478 ISDHECQELQRLTNVAATSGDGYRGQTSPHTPNEKFYGVTVFKALKLGQEGKVPLQSAHL 537
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Qy        538 YYNVTEKVRRIMESYFRLDTPLYFSYSHLVCRTAIEEVQAERKDDSHPVHVDNCILNAET 597
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DT   01-OCT-2003 (TrEMBLrel. 25, Last annotation update)
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RA   Wassenhove-McCarthy D.J., McCarthy K.J.;
RT   "Molecular characterization of a novel basement membrane-associated
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RL   J. Biol. Chem. 274:25004-25017(1999).
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Qy         12 LLAV-VAAASQAEVESEAGWGMVTPDLLFAEGTAAYARGDWPGVVLSMERALRSRAALRA 70
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Qy         71 LRLRCRTQCAADFPWELDPDWSPSPA--QASGAGALRDLSFFGGLLRRAACLRRCLGPPA 128
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Db         61 LRLRCRTRCATELPWAPDLDLGPASSLNHDPGAAALHDLRFFGALLRRAACLRRCLGPPS 120

Qy        129 AHSLSEEMELEFRKRSPYNYLQVAYFKINKLEKAVAAAHTFFVGNPEHMEMQQNLDYYQT 188
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Qy        189 MSGVKEADFKDLETQPHMQEFRLGVRLYSEEQPQEAVPHLEAALQEYFVAYEECRALCEG 248
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Qy        249 PYDYDGYNYLEYNADLFQAITDHYIQVLNCKQNCVTELASHPSREKPFEDFLPSHYNYLQ 308
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Qy        429 ETLVEEKTKESLDVSRLTREGGPLLYEGISLTMNSKLLNGYQRVVMDGVISDHECQELQR 488
              |||||||||||||||||||||||||||||:||||||:||| |||||||||| |||||||
Db        421 ETLVEEKTKESLDVSRLTREGGPLLYEGINLTMNSKVLNGSQRVVMDGVISDDECQELQR 480

Qy        489 LTNVAATSGDGYRGQTSPHTPNEKFYGVTVFKALKLGQEGKVPLQSAHLYYNVTEKVRRI 548
              ||| |||||||||||||||||||||||||||| ||||||||||||:|||||||||||||:
Db        481 LTNAAATSGDGYRGQTSPHTPNEKFYGVTVLKALKLGQEGKVPLQSAHMYYNVTEKVRRV 540

Qy        549 MESYFRLDTPLYFSYSHLVCRTAIEEVQAERKDDSHPVHVDNCILNAETLVCVKEPPAYT 608
              |||||||||||||||||||||||| |||||| ||||||||||||:|||:|||||||
Db        541 MESYFRLDTPLYFSYSHLVCRTAIEESQAERKDSSHPVHVDNCILNAESLVCIKEPPAYT 600

Qy        609 FRDYSAILYLNGDFDGGNFYFTELDAKTVTAEVQPQCGRAVGFSSGTENPHGVKAVTRGQ 668
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        601 FRDYSAILYLNGDFDGGNFYFTELDAKTVTAEVQPQCGRAVGFSSGTENPHGVKAVTRGQ 660

Qy        669 RCAIALWFTLDPRHSERDRVQADDLVKMLFSPEEMDLSQEQPLDAQQGPPEPAQESLSGS 728
              ||||||||||||||||||||||||||||||||||:|| |||||  ||| |:| :||||
Db        661 RCAIALWFTLDPRHSERDRVQADDLVKMLFSPEEVDLPQEQPLPDQQGSPKPGEESLSDR 720
```

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Qy        729 ESKPKDEL 736
              ||:|||||
Db        721 ESQPKDEL 728
```

```
RESULT 8
Q9QZT7
ID   Q9QZT7      PRELIMINARY;      PRT;   747 AA.
AC   Q9QZT7;
DT   01-MAY-2000 (TrEMBLrel. 13, Created)
DT   01-MAY-2000 (TrEMBLrel. 13, Last sequence update)
DT   01-OCT-2003 (TrEMBLrel. 25, Last annotation update)
DE   Growth suppressor 1L.
GN   LEPRE1 OR GROS1.
OS   Mus musculus (Mouse).
OC   Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC   Mammalia; Eutheria; Rodentia; Sciurognathi; Muridae; Murinae; Mus.
OX   NCBI_TaxID=10090;
RN   [1]
RP   SEQUENCE FROM N.A.
RC   STRAIN=CD1 ICR; TISSUE=Fibroblast;
RX   MEDLINE=20406537; PubMed=10951563;
RA   Kaul S.C., Sugihara T., Yoshida A., Nomura H., Wadhwa R.;
RT   "Gros1, a potential growth suppressor on chromosome 1: its identity to
RT   basement membrane-associated proteoglycan, leprecan.";
RL   Oncogene 19:3576-3583(2000).
DR   EMBL; AF165163; AAF04806.1; -.
DR   MGD; MGI:1888921; Lepre1.
DR   GO; GO:0005737; C:cytoplasm; IDA.
DR   GO; GO:0005634; C:nucleus; IDA.
DR   GO; GO:0016049; P:cell growth; IDA.
DR   InterPro; IPR005123; 2OG-FeII_Oxy.
DR   InterPro; IPR006620; Pro_4_hyd_alph.
DR   InterPro; IPR008941; TPR-like.
DR   Pfam; PF03171; 2OG-FeII_Oxy; 1.
DR   SMART; SM00702; P4Hc; 1.
SQ   SEQUENCE   747 AA;  84811 MW;  EBEAB2A62E824123 CRC64;

  Query Match           85.7%;  Score 3316;  DB 11;  Length 747;
  Best Local Similarity  88.2%;  Pred. No. 7.4e-241;
  Matches  623;  Conservative   33;  Mismatches   48;  Indels    2;  Gaps    1;

Qy         25 ESEAGWGMVTPDLLFAEGTAAYARGDWPGVVLSMERALRSRAALRALRLRCRTQCAADFP 84
              ||| ||  :  ||||:|||||||:| |||||||:|||||||||||||||||||:|| : |
Db         25 ESEPGWDVAAPDLLYAEGTAAYSRRDWPGVVLNMERALRSRAALRALRLRCRTRCATELP 84

Qy         85 WELDPDWSPSP--AQASGAGALRDLSFFGGLLRRAACLRRCLGPPAAHSLSEEMELEFRK 142
              |  | |  | |  :|  || || || ||| :|||||||||||||:|| ||||::||| |
Db         85 WAPDLDLGPDPSLSQDPGAAALHDLRFFGAVLRRAACLRRCLGPPSAHLLSEELDLEFNK 144

Qy        143 RSPYNYLQVAYFKINKLEKAVAAAHTFFVGNPEHMEMQQNLDYYQTMSGVKEADFKDLET 202
              ||||||||||||||||||||||||||||||||:||||||||||||||||:|||
Db        145 RSPYNYLQVAYFKINKLEKAVAAAHTFFVGNPEHMEMRQNLDYYQTMSGVKEADFRDLEA 204

Qy        203 QPHMQEFRLGVRLYSEEQPQEAVPHLEAALQEYFVAYEECRALCEGPYDYDGYNYLEYNA 262
              :||| |||||||||||:|||||||||||||||| ||||||||||||||||||:|:|
Db        205 KPHMHEFRLGVRLYSEEKPQEAVPHLEAALQEYFVADEECRALCEGPYDYDGYNYLDYSA 264

Qy        263 DLFQAITDHYIQVLNCKQNCVTELASHPSREKPFEDFLPSHYNYLQFAYYNIGNYTQAGE 322
              ||||||||:|||||||||||||||||||||||||||||||||||||||||||||||| |
Db        265 DLFQAITDHYVQVLNCKQNCVTELASHPSREKPFEDFLPSHYNYLQFAYYNIGNYTQAIE 324

Qy        323 CAKTYLLFFPNDEVMNQNLAYYAAMLGEEHTRSIGPRESAKEYRQRSLLEKELLFFAYDV 382
              |||||||||||||:|||||| ||||||    || |||:|:|||: :|||||||||||||:
Db        325 CAKTYLLFFPNDEVMHQNLAYYTAMLGEEEASSISPRENAEEYRRRPNLLEKELLFFAYDI 384

Qy        383 FGIPFVDPDSWTPEEVIPKRLQEKQKSERETAVRISQEIGNLMKEIETLVEEKTKESLDV 442
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        385 FGIPFVDPDSWTPEEVIPKRLQEKQKSERETAVRISQEIGNLMKEIETLVEEKTKESLDV 444

Qy        443 SRLTREGGPLLYEGISLTMNSKLLNGYQRVVMDGVISDHECQELQRLTNVAATSGDGYRG 502
              ||||||||||||||||||||:||| |||||||||||| |||||||||| ||||||||||
```

```
Db        445 SRLTREGGPLLYEGISLTMNSKVLNGSQRVVMDGVISDDECQELQRLTNAAATSGDGYRG 504

Qy        503 QTSPHTPNEKFYGVTVFKALKLGQEGKVPLQSAHLYYNVTEKVRRIMESYFRLDTPLYFS 562
              |||||||||||||||| |||||||||||||||| :|||||||||:|||||||||||||||
Db        505 QTSPHTPNEKFYGVTVLKALKLGQEGKVPLQSARMYYNVTEKVRRVMESYFRLDTPLYFS 564

Qy        563 YSHLVCRTAIEEVQAERKDDSHPVHVDNCILNAETLVCVKEPPAYTFRDYSAILYLNGDF 622
              ||| |||||||| |||||| |||||||||||||| :|:|||||||:||||||||||||
Db        565 YSHFVCRTAIEESQAERKDSSHPVHVDNCILNAEAFMCIKEPPAYTFREYSAILYLNGDF 624

Qy        623 DGGNFYFTELDAKTVTAEVQPQCGRAVGFSSGTENPHGVKAVTRGQRCAIALWFTLDPRH 682
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        625 DGGNFYFTELDAKTVTAEVQPQCGRAVGFSSGTENPHGVKAVTRGQRCAIALWFTLDPRH 684

Qy        683 SERDRVQADDLVKMLFSPEEMDLSQEQPLDAQQGPPEPAQESLSGS 728
              |||||||||||||||||||:|| ||||| ||| ||| :| | |:
Db        685 SERDRVQADDLVKMLFSPEEVDLPQEQPLPDQQGSPEPGEEFLHGA 730
```

```
RESULT 9
Q9CWK5
ID   Q9CWK5      PRELIMINARY;      PRT;   742 AA.
AC   Q9CWK5;
DT   01-JUN-2001 (TrEMBLrel. 17, Created)
DT   01-JUN-2001 (TrEMBLrel. 17, Last sequence update)
DT   01-OCT-2003 (TrEMBLrel. 25, Last annotation update)
DE   2410024C15Rik protein.
GN   LEPRE1 OR GROS1 OR 2410024C15RIK.
OS   Mus musculus (Mouse).
OC   Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC   Mammalia; Eutheria; Rodentia; Sciurognathi; Muridae; Murinae; Mus.
OX   NCBI_TaxID=10090;
RN   [1]
RP   SEQUENCE FROM N.A.
RC   STRAIN=C57BL/6J; TISSUE=Embryonic stem cells;
RX   MEDLINE=21085660; PubMed=11217851;
RA   Kawai J., Shinagawa A., Shibata K., Yoshino M., Itoh M., Ishii Y.,
RA   Arakawa T., Hara A., Fukunishi Y., Konno H., Adachi J., Fukuda S.,
RA   Aizawa K., Izawa M., Nishi K., Kiyosawa H., Kondo S., Yamanaka I.,
RA   Saito T., Okazaki Y., Gojobori T., Bono H., Kasukawa T., Saito R.,
RA   Kadota K., Matsuda H.A., Ashburner M., Batalov S., Casavant T.,
RA   Fleischmann W., Gaasterland T., Gissi C., King B., Kochiwa H.,
RA   Kuehl P., Lewis S., Matsuo Y., Nikaido I., Pesole G., Quackenbush J.,
RA   Schriml L.M., Staubli F., Suzuki R., Tomita M., Wagner L., Washio T.,
RA   Sakai K., Okido T., Furuno M., Aono H., Baldarelli R., Barsh G.,
RA   Blake J., Boffelli D., Bojunga N., Carninci P., de Bonaldo M.F.,
RA   Brownstein M.J., Bult C., Fletcher C., Fujita M., Gariboldi M.,
RA   Gustincich S., Hill D., Hofmann M., Hume D.A., Kamiya M., Lee N.H.,
RA   Lyons P., Marchionni L., Mashima J., Mazzarelli J., Mombaerts P.,
RA   Nordone P., Ring B., Ringwald M., Rodriguez I., Sakamoto N.,
RA   Sasaki H., Sato K., Schoenbach C., Seya T., Shibata Y., Storch K.-F.,
RA   Suzuki H., Toyo-oka K., Wang K.H., Weitz C., Whittaker C., Wilming L.,
RA   Wynshaw-Boris A., Yoshida K., Hasegawa Y., Kawaji H., Kohtsuki S.,
RA   Hayashizaki Y.;
RT   "Functional annotation of a full-length mouse cDNA collection.";
RL   Nature 409:685-690(2001).
DR   EMBL; AB010578; BAB27041.1; -.
DR   MGD; MGI:1888921; Lepre1.
DR   GO; GO:0005737; C:cytoplasm; IDA.
DR   GO; GO:0005634; C:nucleus; IDA.
DR   GO; GO:0016049; P:cell growth; IDA.
DR   InterPro; IPR005123; 2OG-FeII_Oxy.
DR   InterPro; IPR006620; Pro_4_hyd_alph.
DR   InterPro; IPR008941; TPR-like.
DR   Pfam; PF03171; 2OG-FeII_Oxy; 1.
DR   SMART; SM00702; P4Hc; 1.
SQ   SEQUENCE   742 AA;  84086 MW;  CFC44D34D96ACEA7 CRC64;

  Query Match           85.4%;  Score 3305;  DB 11;  Length 742;
  Best Local Similarity  86.0%;  Pred. No. 4.9e-240;
  Matches  629;  Conservative   37;  Mismatches   57;  Indels    8;  Gaps    3;

Qy          1 MAVRALKLLTTLLAVVAAAS-QAEVESEAGWGMVTPDLLFAEGTAAYARGDWPGVVLSME 59
```

Exhibit B

protein of Daigo et al.

GenCore version 5.1.6
Copyright (c) 1993 - 2004 Compugen Ltd.

OM protein - protein search, using sw model

Run on: August 4, 2004, 08:49:58 ; Search time 1 Seconds
(without alignments)
1.292 Million cell updates/sec

Title: US-10-045-815-4
Perfect score: 3870
Sequence: 1 MAVRALKLLTTLLAVVAAAS.....PPEPAQESLSGSESKPKDEL 736

Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 1 seqs, 1755 residues ← PLC1 gene product

Total number of hits satisfying chosen parameters: 1

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 1 summaries

Database : baa77247.genpept:*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	% Query Match	Length	DB	ID	Description
1	56	1.4	1755	1	BAA77247	

ALIGNMENTS

RESULT 1
BAA77247

Query Match 1.4%; Score 56; DB 1; Length 1755;
Best Local Similarity 18.7%; Pred. No. 0;
Matches 29; Conservative 25; Mismatches 53; Indels 48; Gaps 6;

```
Qy      390 PDSWTPEEVIPKRLQEKQKSERETAVRIS-QEIGNLMKEIETLVEEKTKESLDVSRLTRE 448
            ||  |   ::|::      :: |  :  |  |: :    :: ::||  :
Db      673 PDKETAFSIMPRKGVLSPHTDHEFILSFSPHELRDFHSVLQMVLEEVPE---------- 721

Qy      449 GGPLLYEGISLTMNSKLLNGYQRVVMDGVISDHECQELQRLTNVAATSGDGYRGQTSPH- 507
              |:  |  ||       |:    :| ||      |::          :|    |
Db      722 --PVSSEAESL--------GHSSYSVDDVI----VLEIE-----------VKGSVEPFQ 755

Qy      508 ---------TPNEKFYGVTVFKALKLGQEGKVPLQ 533
                    | | : |: | || |:    | |::
Db      756 VLLEPYALIIPGENYIGINVKKAFKMWNNSKSPIR 790
```

Search completed: August 4, 2004, 08:50:01
Job time : 1 secs

Exhibit C

PT infectious diseases such as malaria or cancer.
XX
PS Claim 5; Page 52; 72pp; Japanese.
XX
CC The present invention describes a fused protein (I) prepared from a
CC peptide containing a CTL (cytotoxic T lymphocyte) epitope recognised by
CC cytotoxic T cells and a protein containing the ATPase domain of a heat
CC shock protein. Also described are: (1) a drug composition containing (I)
CC as active ingredient; (2) a DNA encoding (I); (3) an expression vector
CC containing the DNA of (2); and (4) a transformant which can retain the
CC expression vector of (3). (I) has cytostatic, immunostimulant and
CC protozoacide activities, and can be used as a cellular immune response
CC inducer. The protein is useful as an active ingredient for drug
CC compositions in preventing and/or treating infectious diseases such as
CC malaria or cancer e.g. to provide systemic immunity against leukaemia.
CC The present sequence represents a specifically claimed CTL epitope for
CC use in a fused protein of the present invention
XX
SQ Sequence 8 AA;

Query Match 0.8%; Score 6; DB 3; Length 8;
Best Local Similarity 100.0%; Pred. No. 1.4e+06;
Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 731 KPKDEL 736
||||||
Db 1 KPKDEL 6

RESULT 10
ADE80013
ID ADE80013 standard; peptide; 8 AA.
XX
AC ADE80013;
XX
DT 29-JAN-2004 (first entry)
XX
DE Malaria CTL epitope in method to generate CD8+ T-cell immune response.
XX
KW antimalarial; cytostatic; vaccine; immune response;
KW non-hepadnaviral antigen; hepatitis B core particle; CD8+ T-cell;
KW epitope; poxvirus vector; cancer; malaria; epitope.
XX
OS Plasmodium falciparum.
XX
PN WO2003066833-A2.
XX
PD 14-AUG-2003.
XX
PF 07-FEB-2003; 2003WO-US003897.
XX
PR 08-FEB-2002; 2002US-0354963P.
XX
PA (UYNY-) UNIV NEW YORK MEDICAL CENT.
XX
PI Zavala F, Birkett AJ;
XX
DR WPI; 2003-748124/70.
XX
PT Generating an immune response against a non-hepadnaviral antigen in a
PT mammal, useful for treating or preventing cancer or malaria, by
PT administering a priming component comprising a recombinant hepatitis B
PT core particle.
XX
PS Disclosure; SEQ ID NO 69; 85pp; English.
XX
CC The invention relates to a method of generating an immune response
CC against a non-hepadnaviral antigen in a mammal by administering (to the
CC mammal) at least 1 dose of a priming component comprising a recombinant
CC hepatitis B core particle (rHEP) (which is a carrier for 1 or more non-
CC hepadnaviral CD8+ T-cell epitopes of the antigen). The method may be
CC supplemented by the use of a boosting stage comprising a non-replicating
CC or replication-impaired recombinant poxvirus vector. The method is useful
CC for generating an immune response against a non-hepadnaviral antigen in a
CC mammal for treating or preventing cancer or malaria. This sequence
CC represents a Plasmodium falciparum CTL peptide used to generate an immune
CC response against a Plasmodium peptide.
XX
SQ Sequence 8 AA;

Query Match 0.8%; Score 6; DB 7; Length 8;
Best Local Similarity 100.0%; Pred. No. 1.4e+06;
Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 731 KPKDEL 736
||||||
Db 1 KPKDEL 6

RESULT 11
AAP90014
ID AAP90014 standard; protein; 5 AA.
XX
AC AAP90014;
XX
DT 25-MAR-2003 (revised)
DT 01-NOV-1989 (first entry)
XX
DE Peptide from HLA Class II beta region contg. residue corresp. tp DQ-beta
DE protein.
XX
KW Peptide; DQ-beta locus of HLA class II beta genes; allele-specific.
XX
OS Homo sapiens.
XX
PN WO8904875-A.
XX
PD 01-JUN-1989.
XX
PF 14-NOV-1989; 89WO-US004067.
XX
PR 17-NOV-1987; 87US-00121519.
XX
PA (CETU) CETUS CORP.
XX
PI Erlich HA, Horn GT;
XX
DR WPI; 1989-178393/24.
XX
PT Marker DNA sequences from HLA class-II beta region - detect amino acid 57
PT codon of dq-beta protein to detect auto-immune susceptibility.
XX
PS Claim 14; Page 59; 72pp; English.
XX
CC Peptide contg. an epitope which has an amino acid residue corresp. to
CC position 57 of a DQ-beta protein from the HLA class II beta genes, used
CC to raise antibodies to (in)directly detect the identity of codon-57 of
CC the DQ-beta protein sequence. Pref. codon-57 is selected from Ala, Val
CC and Asp. Used to detect autoimmune diseases, esp. diabetes mellitus, and
CC Pemphigus vulgaris. (Updated on 25-MAR-2003 to correct PF field.)
XX
SQ Sequence 5 AA;

Query Match 0.7%; Score 5; DB 1; Length 5;
Best Local Similarity 100.0%; Pred. No. 1.4e+06;
Matches 5; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 125 GPPAA 129
|||||
Db 1 GPPAA 5

RESULT 12
AAW00426
ID AAW00426 standard; peptide; 5 AA.
XX